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| 10/048,035 | 06/11/2002 | Wolf Bertling | 10848-017001 | 1180 |

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| EXAMINER | |
|---|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/048,035 | BERTLING ET AL. | |
| | Examiner | Art Unit | |
| | Sarae Bausch | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01/22/2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of group I (claims 1-27) in the reply filed on 10/01/2004 is acknowledged. The response provides no arguments with the traversal regarding the restriction requirement. The requirement is still deemed proper and is therefore made FINAL.

2. Claim 28 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/01/2004.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a method for labeling and identifying a solid, liquid, and gaseous substance. However, the final process step is detecting hybridization of two nucleic acid molecules. Accordingly, it is unclear as to whether the claim is intended to be limited to hybridization of nucleic acid molecules or for labeling and identifying a solid, liquid, and gaseous substance as referred to in the preamble. Applicants should amend the claim to indicate how the step of hybridization of nucleic acid molecules results in the labeling and identifying a solid liquid and gaseous substance.

5. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 recites the method of claim 1 wherein the second group of nucleic acid molecules is bound to a predefined site on a solid surface, however it is unclear how the second group of nucleic acid molecules can be bound to a solid surface if the first set of nucleic acid molecules are also contacting a substance that is a solid support, if the substance is broadly interpreted to encompass a solid support.

6. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 is drawn to a method for identifying a solid, liquid, and gaseous substance. However, the final process step is detecting hybridization of two nucleic acid molecules. Accordingly, it is unclear as to whether the claim is intended to be limited to hybridization of nucleic acid molecules or for identifying a solid, liquid, and gaseous substance as referred to in the preamble. Applicants should amend the claim to indicate how the step of hybridization of nucleic acid molecules results in identifying a solid liquid and gaseous substance.

### *Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6, 8-9, 12-13, 20, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sano et al. (US Patent 5665539, Sept. 1997). Sano et al. teach a method of immuno-polymerase chain reaction in which a biotinylated nucleic acid molecule is used as a marker.

With regards to claims 1, 8, 9, 12, and 27, Sano et al. teach a method of making a chimera-pUC19 conjugate by mixing a purified chimera, streptavidin protein A chimera, and a biotinylated puc19 (instant claim 8 and 9) which results in four biotinylated pUC19 per chimera (first group of predefined nucleic acid molecules) (instant claim 12) (see column 11, lines 3-18). Sano et al. teach the method of adding the chimera-pUC19 (selecting at least one nucleic acid and contacting the substance with one predefined nucleic acid) conjugate to each microtiter well (substance) and subjecting the mixture to PCR (see column 11, lines 4-12). Sano et al. teach using PCR amplification of the bla gene by using two 30-mer primers, bla-1 and bla-2 that hybridized to a segment of the bla gene (providing a second group of nucleic acid, wherein the second group of nucleic acid comprises a detection sequence section (bla-1 and bla-2) complementary to one of the identification sequences (bla gene) and detect hybridization (PCR)) (see column 12, lines 1-10).

With regard to claims 2-4, 6, and 24, Sano et al. teach using PCR amplification (instant claim 6 and ~~26~~ 24) to generate a 261 bp fragment of the bla gene using bla-1 and bla-2 primers (identification sequence section located between two primer binding sections, comprising two complementary identification sequence sections (double stranded DNA)) (see column 12, lines 9-10 and figure 1).

11/15

With regard to claim 13, Sano et al. teach a method of conjugating a biotinylated pUC19 to a streptavidin-protein A chimera and adding to a microtiter well followed by subjecting the reaction to PCR (predefined nucleic acid molecules are bound to particles) (see column 11, lines 3-11).

With regard to claim 20, Sano et al. teach the method of synthesizing PCR primers by β-cyanoethyl phosphoramide chemistry using an automated DNA synthesizer (second group of nucleic acid molecules prepared synthetically) (see column 6, lines 11-14).

With regard to claim 26, Sano et al. teach primers that hybridize to a segment of the bla gene and generate a 261 bp fragment (identification sequence sections comprise primer binding sequence sections) (see column 6, lines 22-24).

9. Claims 1-11, 13-15, 20, 24, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Slater et al. (WO 94/04918 March 1994). Slater et al. teach a method of detecting the liquid that has been marked by a nucleic acid tag.

With regard to claim 1 and 27, Slater et al. teach the method of tagging substances with a taggant (see page 24, lines 6-8), that can either be a naturally occurring or synthetic nucleic acids (contacting the substance with at least one predefined nucleic acid molecule) (see page 24, lines 32-36) that are capable of forming duplexes with PCR primers and function as a template for polymerases used in PCR (see page 25, lines 22-25). Slater et al. teach a taggant DNA that is 70-90 base pairs with 30 nucleotides on either end constant to carry pre-determined sequences which recognize appropriate complementary primers for PCR amplification and DNA sequencing and middle region is variable with a unique, characteristic signal (nucleic acid molecule from a group of predefined nucleic acid molecules wherein the each predefined nucleic

acid molecule comprises an identification sequence section) (see page 27, lines 2-23). Slater et al. teach detecting the nucleic acid by PCR (detecting hybridization) using primer G-18 and primer G-19 (providing a second group of nucleic acid molecules which comprise a detection sequence section complementary to one of the identification sequence sections) (see page 27, lines 28-32 and page 28, lines 4-7).

With regard to claim 2-4, Slater et al. teach a taggant double stranded DNA with two regions that carry pre-determined sequences that recognize appropriate complementary primers and middle region of DNA that is variable for a unique characteristic signal (identification sequence located between two primer binding sections, identification sequence contains two identification sequence sections complementary to each other) (see page 27, lines 11-19).

With regard to claim 5, Slater et al. teach primer G-18, which is the exact complement of the primer binding site and the complement primer G-19, which is the exact complement of the second primer binding site. The primers have the same melting point since each primer is the exact complement of the primer binding site (see page 27, lines 28-31 and page 28, lines 4-7).

With regard to claim 6 and 24, Slater et al. teach detection of nucleic acid by PCR (amplification) (see page 27, line 15-16, and page 28, lines 12-17).

With regard to claim 7-9, Slater et al. teach a biotin CPG attached to the 3' end of the taggant (biotin coupling group) (see page 27, line 20-22 and page 28, lines 8-12). The 3' end of the taggant is attached to an agent, biotin, that counteracts degradation by an exonuclease by protecting the 3' end of the nucleic acid.

With regard to claim 10 and 11, Slater et al. teach labeling the nucleoside base of the DNA with a hydrophobic hapten, such as fluorescein (fluorophoric group bound to predefined

nucleic acid molecule and hapten coupling group labeled with fluorophoric group) (see page 31, lines 4-6).

With regard to claim 13, Slater et al. teach a taggant (predefined nucleic acid molecule) labeled with biotin to couple taggant to microbeads coated with streptavidin (see page 27, lines 20-23 and page 28, lines 8-11).

With regard to claim 14-15, Slater et al. teach a taggant (predefined nucleic acid molecule) attached to paramagnetic carboxyl-modified polystyrene beads (see page 29, lines 24-29) with a typical size of .1 to 1μm (see page 29, lines 18-20).

With regard to claim 20, Slater et al. teach a taggant (predefined nucleic acid molecule) that is a synthetic double stranded DNA sequence of 70 to 90 base pairs (see page 27, lines 3-5).

10. Claims 1, 7-10, 13, 15, 17, 18, 20-23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantor et al (US Patent 5795714 Aug 1998).
Cantor et al. teach a method of replicating a probe array to screen biological samples for specific target sequences.

With regard to claim 1 and 27, Cantor et al. teach synthesizing one or more sets of nucleic acid probes simultaneously on a solid support (contacting (labeling) the substance (solid support) with at least one predefined nucleic acid molecule) (see column 8, lines 37-40). Cantor et al. teach a method comprising creating a set of nucleic acid probes (first group of predefined nucleic acid molecules), wherein each probe has a double stranded portion, a single stranded portion, and a random sequence within the singe stranded portion (selecting at least one nucleic acid molecule) which is hybridized to a nucleic acid target (providing a second group of nucleic

acid molecules with a detection sequence and contacting the substance (first group of predefined nucleic acid molecules attached to a solid support) with the nucleic acid molecules provided from the second group under predefined hybridization conditions) to the set of nucleic acid probes and determining the nucleotide sequence of the target which hybridized to the single stranded portion of any probe (detecting hybridization) (see column 7, lines 11-20).

With regard to claim 7-9, Cantor et al. teach attaching the nucleic acid probe to a solid support by immobilized 5'-labeled biotinylated DNA strands (coupling group, biotin) that consists of a variable 5 or 6 base segment plus the constant 15 base segment (see column 21, lines 59-66). The 5' labeled biotinylated DNA strand counteracts degradation caused by an exonuclease by protecting the 5' to exposure to the exonuclease.

With regard to claim 10, Cantor et al. teach the probe or the array of probes labeled with a fluorescent chemical (see column 9, lines 4-6 and lines 20-26).

With regard to claim 13 and 15, Cantor et al. teach one 5' end biotinylated strand of the probe duplex (predefined nucleic acid molecule) is attached to a solid surface (see column 19, lines 34-40) and teach moderately dense arrays can be made using a typical X-Y robot to spot the biotinylated compounds individually (predefined nucleic acid molecules) onto a streptavidin coated surface (particle) and streptavidin-coated beads can be adhered, permanently to plastics like polystyrene (instant claim 15) (see column 20, lines 65-67, column 21 lines 1-9).

With regard to claim 17, Cantor et al. teach biotinylated double stranded probes (first nucleic acid group) attached to streptavidin coated beads adhered to polystyrene surface by spotting biotinylated compounds individually onto the streptavidin coated surface (predefined sites on substance, solid support) followed by hybridization of the target sequence to the probe

by annealing and ligating the target sequence to the probe attached to the polystyrene beads (see column 20, lines 66-67, column 21, lines 1-8 and see column 31, lines 53-67) (second group of nucleic acid molecules bound to a predefined site on a solid surface).

With regard to claim 18, Cantor et al. teach a labeled probe or target molecule with a fluorescent chemical that may be directly or indirectly detected using scintillation fluid or a PhosphorImager, chromatic or fluorescent labeling or mass spectrometry (see column 9, lines 4-7 and lines 14-26) (complementary detection sequence detected by means of fluorescence).

With regard to claim 20, Cantor et al. teach the nucleic acids may be artificially synthesized (see column 6, lines 43-47).

With regard to claim 21 and 22, Cantor et al. teach the set of nucleic acid probes (first group of nucleic acid molecules) and target nucleic acid (second group of nucleic acid molecules) comprise PNA (nucleic acid analog) (see column 7, lines 20-24).

With regard to claim 23, Cantor et al. teach a target nucleic acid hybridized to a probed attached to a solid support, such as plastic, ceramic, metal, resin, film or other polymer, gel, membrane, or two or three dimensional array such as a chip or microchip (see column 12, lines 56-67).

11. Claims 1,2, 6, 16, 18, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Bumstead et al. (J. Virological Methods 65 (1997) 75-81). Bumstead et al. teach a quantitative assay to determine the number of viral genomes present in samples by PCR amplification of the viral genome using fluorescent-tagged primers (abstract).

With regard to claim 1, Bumstead et al. teach 2μl cells (first group of predefined nucleic acid molecules) in a volume of 25ml PCR reaction (substance) with 10pmol of primer (second

group of nucleic acid molecules, wherein each nucleic acid molecule comprises a detection sequence section complementary to one of the identification sequences and contacting the substance with the nucleic acid molecules under predefined hybridization conditions). Bumstead et al. teach primers used to detect MDV to amplify a product of 279 bp (identification sequence of the predefined nucleic acid molecules). Bumstead et al. teach amplification of the PCR reaction and quantification of products of PCR by electrophoresis on a sequencer (detecting hybridization). (see section 2.2 page 76-77).

With regard to claim 2, Bumstead et al. teach primers used to amplify a product of 279 bp (identification sequence located between two primer binding sequence sections). (see section 2.2 page 76)

With regard to claim 6 and 24 , Bumstead et al. teach amplification of product 279 of MDV by two primers by PCR. (see section 2.2 page 76-77)

With regard to claim 16, Bumstead et al. teach amplification of Marek's disease virus (particle), a herpes virus (abstract), from cells by PCR. The cells contain MDV and were not purified. The MDV contains the 279 bp region of the MDV genome. Bumstead teaches a particle (MVD virus) that is a virus-like particle included in the predefined nucleic acid molecule (MVD genome) (1st paragraph, 2nd column, page 76 and section 2.2, page 76-77).

With regard to claim 18, Bumstead et al. teach quantification of the fluorescent bands from the PCR products by ABI Genescna software (detection by fluorescence of the hybridization of the identification sequence section with the complementary detection sequence section) (see 1st paragraph, 1st column, page 77).

With regard to claim 25, Bumstead et al. teach the use of fluorescently labeled primer, primer 1 (1st paragraph, section2.2, page 76).

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
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